

REMARKS

This amendment is in response to the Final Office Action of October 4, 2004, which rejected claims 1-7 under 35 U.S.C. Section 102(b) as being anticipated by Paraschac, U.S. Statutory Invention Registration H1745. A Request for Continued Examination and RCE fee accompanies this amendment.

In the present invention, claims 1 and 3 are independent. Dependent claims 2 and 4-7 depend from one of claims 1 or 3. Claims 1 and 3 have been amended to further clarify the claimed invention and are respectfully believed to be patentable in view of the cited reference to Paraschac.

The structure and function of Applicant's invention is fundamentally different from the structure and function of Paraschac. Applicant's invention, as set forth in the present claims, is directed to an apparatus for forming non-conductive lines of ablation in tissue, such as cardiac tissue, without excessive tissue damage. The conductive electrodes are substantially narrower than the clamping surface, of which they form a part. Applicant's disclosure explains several advantages of the claimed electrode/jaw arrangement. For example, at page 16, lines 2-7 of the 2nd full paragraph, applicant's specification discloses that:

Importantly, Figure 9 shows that the electrode/clamp configuration provides a clamped zone of tissue that is wider than the zone of ablated tissue. This is

achieved by using an electrode width that is narrower than the clamped tissue width, and preferably less than one-third of the clamped tissue width. (emphasis added)

Examples of applicant's electrode/clamp configuration is shown and described in the original specification in Figures 9, 21, 26 and 38-51 and at pages 16-20. Applicant's disclosure further describes that the narrower ablation zone of the claimed invention minimizes the risks associated with thrombus. At page 16, last paragraph, applicant's disclosure states:

The wider zone of clamped tissue serves several purposes. When the clamping members are closed onto tissue, any blood in the clamped zone is squeezed or expressed out. Further, the distance between the electrodes is minimized, so that the ablation zone remains narrow. It is important to isolate the blood from the ablation zone to avoid creating thrombus. Accordingly, a clamped zone that isolates the ablation zone from the blood minimizes the temperature at the periphery of the ablation zone and will reduce the likelihood of the formation of thrombus by the blood in contact with the clamped zone. (emphasis added).

Applicant's disclosure specifically teaches away from thrombus formation by providing a narrower ablation zone than the clamping zone.

In addition, the pending claims require that the jaw members, including a clamping surface of which the respective electrode forms a part, are parallel through a range of clamping motion. Examples of apparatus with this feature are shown in applicant's specification at Figures 1, 7, 18, 20, 25 and 33-37

and are described at page 11, lines 11-14 and line 32 and page 21, lines 22-27. Such feature provides that "the spacing between the jaws [is] substantially uniform or constant" (page 21, lines 26-27). Uniform spacing is understood to provide more uniform current between the electrodes and through the tissue during ablation.

Paraschac Does Not Teach Or Suggest Claimed Features

Paraschac intentionally discloses a structure which provides coagulation along the entire width of the jaw, and, in some circumstances, beyond the width of the jaw. Paraschac does not disclose or suggest narrow electrodes. Each of Figures 1-3 of Paraschac discloses an end effector having electrodes which provides a coagulation current that is at least as wide as the width of the end effector, unlike the present invention.

Paraschac's instrument is clearly different in structure and function as compared to the claimed invention. Specifically, Paraschac discloses an electrosurgical hemostatic grasping instrument which is used to grasp, treat and cut tissue and blood vessels to cause coagulation (column 1, lines 6-16). The hemostatic instrument of Paraschac uses electrical current between the entire widths of the jaws of the end effector "to reduce bleeding along a cut line prior to cutting tissue" (column 1, lines 64-65).

Paraschac teaches that it is beneficial "to develop a substantially uniform electrical field through the tissue between the end effectors" (Column 2, lines 9-10) (emphasis added). The wide hemostatic treatment zone of Paraschac, as clearly shown in Figures 1-3, has the very opposite purpose and result as contrasted to the much narrower ablation zone provided in the claimed invention.

In fact, applicant emphasizes that Paraschac specifically requires that the electrical current coagulates the tissue extending outside the jaws, such as shown in Figure 3. Paraschac expressly requires that his invention "create a selective region of visible coagulation around the end effector to provide visual feedback to the surgeon" so that the surgeon determines when to stop the electrical current. (column 7, lines 1-3) (emphasis added). Thus, Paraschac teaches away from a treatment zone which is substantially narrower than the jaws.

Turning to the particular rejection based on the structures shown in Figures 2 and 3, applicant addresses each structure in turn. In Figure 2, Paraschac's electrodes 11 and 12 are disposed to create electrical current lines, as indicated at 14. Figure 2 of Paraschac shows an electrode/jaw arrangement that creates a treatment zone 14 which is essentially as wide as the jaw. This is contrary to the present invention which, as discussed above, provides electrodes which are narrower than the

clamping surfaces of the jaws and activates the electrodes to create a line of ablation between the electrodes which is substantially narrower than the width of the clamping surface.

It would not be obvious to modify Paraschac's electrodes in Figure 2. Where is the motivation? First, Paraschac is concerned with an entirely different structure and treatment procedure for coagulating or clotting blood prior to cutting tissue. Applicant's specification specifically teaches the avoidance of blood clotting. Second, Paraschac specifically requires that the hemostatic treatment zone must be slightly wider than the clamping surfaces of each jaw to provide visual feedback to the surgeon. Throughout Paraschac's disclosure, there is no teaching or motivation in Paraschac to provide electrodes which are substantially narrower than the clamping surface of the jaws, as recited in the pending claims.

In addition to the above, there are other differences between the structure of Figure 2 and the claimed subject matter. Figure 2 of Paraschac shows first and second electrodes 11 and 12 which are disposed along the three exterior sides of the respective jaw. There is no clamping surface which flanks the electrodes 11 and 12, in contrast to the claims. Rather, the opposite arrangement is shown in which each electrode 11 and 12 flanks the insulators 16 and 18. The insulators 16 and 18 are disposed in between the slight marginal edges of the

electrodes 11 and 12.

In Figure 2, a third electrode 17 also fails to teach or suggest the electrode/jaw arrangement required by the claims. Paraschac clearly teaches that the third electrode 17 must be combined with at least one of the other exterior electrodes 11 and 12 (Column 2, lines 45-48). One electrode 11 is laterally spaced from each side edge of the third electrode 17 and is not even disposed on the opposed jaw from the electrode 17. The other electrode 12 is laterally offset from each side edge of the third electrode 17. The third electrode 17 is not in face-to-face relationship with either one of the electrodes 11 and 12, in contrast to the claimed subject matter.

Further, the electrodes of Figure 2 of Paraschac are different than the claimed subject matter for another reason. In Paraschac, the electrodes 11 and 12 must have the same polarity which is opposite to the polarity to the third electrode 17 otherwise the electrical current in Paraschac would not flow. This is very different from the pending claims which require that the face-to-face electrodes are of opposite polarity.

For all the above reasons, Figure 2 of Paraschac fails to teach or suggest each of the above features, either alone or in combination.

Turning now to the structure of Figure 3, Paraschac's electrodes 21 and 22 are each disclosed as forming opposed planar grasping surfaces 27 and 39, respectively, which span virtually the entire width of the jaw. Thin insulators 26 and 28, respectively, surround the outer surfaces of the electrodes 21 and 22 and provide only a thin, marginal edge on either side of the respective electrode 21 and 22.

In contrast to the claimed invention, the width of the portion of each electrode 21 and 22 that contacts the tissue is not substantially narrower than the width of the clamping surface of each jaw. In fact, Figure 3 shows an arrangement having the very opposite purpose and result in which the electrodes 21 and 22 form essentially the entire width of each jaw's clamping surface. Further, the electrodes 21 and 22 in Figure 3 create a treatment zone 24 which is clearly shown to be wider than the width of each jaw, in contrast to the pending claims.

**Paraschac Does Not Teach Or Suggest Jaws Parallel Through Range
Of Tissue Clamping Spacing**

Each of the end effectors shown in Figures 2-3 is fundamentally different from the claimed subject matter for another reason. Each end effector does not teach or suggest that the jaws are parallel through a range of clamping spacing, as required by the claims. Rather, each end effector is

disclosed only with respect to an instrument having pivotable jaws, as shown in Figure 4. Paraschac omits disclosure of jaws of any other type. Accordingly, Paraschac does not disclose or suggest jaws which are parallel through a range of clamping spacing, either alone or in combination with the other claimed subject matter.

Conclusion

For all the above reasons, it is respectfully requested that the claimed subject matter is not anticipated by and would not have been obvious to a person of ordinary skill in view of Paraschac. It is further respectfully requested that the pending claims, as amended, be reconsidered and allowed.

Respectfully submitted,

Date: January 4, 2005

By: 

Renée C. Barthel, Esq.
Registration No. 48,356
Cook, Alex, McFarron, Manzo,
Cummings & Mehler, Ltd.
200 West Adams St., Ste. 2850
Chicago, IL 60606
Telephone: (312) 236-8500
Attorneys for Applicant